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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,358	10/16/2001	Rembert Pieper	42521	3368

1609 7590 08/10/2004

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EXAMINER

VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,358

Applicant(s)

PIEPER ET AL.

Examiner

David J Venci

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/09/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to an affinity binding composition, classified in class 435, subclass 7.8, for example.
- II. Claims 1, 2 and 9, drawn to an affinity column comprising a third receptor, classified in class 435, subclass 288.6, for example.
- III. Claims 1, 6 and 10-11, drawn to an affinity column comprising an antibody, classified in class 435, subclass 7.1, for example.
- IV. Claims 1, 7 and 12, drawn to an affinity column comprising a porous matrix, classified in class 210, subclass 656, for example.
- V. Claims 1 and 8, drawn to an affinity column, classified in class 422, subclass 70, for example.
- VI. Claim 13, drawn to an apparatus, classified in class 435, subclass 287.1.
- VII. Claims 14-21, drawn to a method for preparing a receptor matrix, classified in class 436, subclass 535, for example.
- VIII. Claims 22-23, drawn to an apparatus, classified in class 435, subclass 287.2, for example.
- IX. Claim 24, drawn to a method for preparing a receptor matrix, classified in class 436, subclass 523, for example.
- X. Claims 25-26, drawn to a method for forming a covalent bond between two proteins, classified in class 436, subclass 532, for example.
- XI. Claims 27-42 and 44 drawn to a method for separating ligands, classified in class 436, subclass 501, for example.
- XII. Claim 43, drawn to an electrophoresis gel, classified in class 210, subclass 658, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombination and combination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because a chamber having an inlet and outlet has separate patentable utility as a centrifugal filtration device, for example. The subcombination of Invention I has separate utility such as a therapeutic delivery composition. This same relationship also applies to Inventions I-III, I-IV, I-V, I-VI, and I-VIII.

Inventions I and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process of Invention VII can be used to make another materially different product, such as a therapeutic delivery composition. This same relationship also applies to Inventions VII-II, VII-III, VII-IV, VII-V, VII-VI, and VII-VIII.

Inventions I and IX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process of Invention IX can be used to make another materially different product, such as a

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therapeutic delivery composition. This same relationship also applies to Inventions IX-II, IX-III, IX-IV, IX-V, IX –VI and IX-VIII.

Inventions I and X are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process of Invention X can be used to make another materially different product, such as a therapeutic delivery composition. This same relationship also applies to Inventions X-II, X-III, X-IV, X-V, X-VI and X-VIII.

Inventions I and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process of Invention XI can be practiced with a materially different product, such as an ion exchange composition. This same relationship also applies to Inventions XI-II, XI-III, XI-IV, XI-V, XI-VI, XI-VIII, and XI-XII.

Inventions (I, II, III, IV, V, VI, VII, VIII, or IX) and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because

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Inventions (I, II, III, IV, V, VI, VII, VIII, or IX) require a receptor, while Invention XII requires an electrophoresis gel.

Inventions X and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention X requires a crosslinking agent, while Invention XII requires an electrophoresis gel.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention II requires a third receptor, while Invention III requires antibodies.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention II requires a third receptor, while Invention IV requires a porous matrix.

Inventions II and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the

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subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because a third receptor immobilized on a solid phase matrix has separate patentable utility as a affinity binding composition, for example. The subcombination of Invention V has separate utility such as a centrifugal filtration device.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention II requires a third receptor, while Invention VI requires a conduit.

Inventions II and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention II requires a third receptor, while Invention VI requires a fluid connection.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention III requires an antibody, while Invention IV requires a porous matrix.

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Inventions III and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because an antibody receptor has separate patentable utility as a affinity binding composition, for example. The subcombination of Invention V has separate utility such as a centrifugal filtration device.

Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention III requires an antibody, while Invention VI requires a conduit.

Inventions III and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention III requires an antibody, while Invention VIII requires a fluid connection.

Inventions IV and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the

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subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because a porous matrix has separate patentable utility as an affinity binding composition, for example. The subcombination of Invention V has separate utility such as a centrifugal filtration device.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention IV requires a porous matrix, while Invention VI requires a conduit.

Inventions IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention IV requires a porous matrix, while Invention VIII requires a fluid connection.

Inventions V and VI are related as subcombination and combination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because a conduit or fluid connection have separate patentable utility as an in-line

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switching valve, for example. The subcombination has separate utility such as a centrifugal filtration device. This same relationship also applies to Inventions V-VIII.

Inventions VI and VIII are related as subcombination and combination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because an immobilized ligand has separate patentable utility as a fluorescent probe, for example. The subcombination has separate utility such as a centrifugal filtration device.

Inventions VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention IX requires a second receptor matrix and Invention VII requires a receptor containing liquid.

Inventions VII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention VII requires the step of eluting, while Invention X requires a crosslinking agent.

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Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention IX requires a matrix, while Invention X requires a crosslinking agent.

Inventions XI and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention XI requires the step of removing ligands, while Invention X requires a crosslinking agent.

Inventions VII and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention VII requires the step of eluting, while Invention XI requires the step of analysis of remaining ligands.

Inventions IX and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention IX requires the step of mixing matrices, while Invention XI requires the step of analysis of remaining ligands.

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Inventions X and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operations because Invention X requires a crosslinking agent, while Invention XI requires the step of analysis of remaining ligands.

Because these inventions are distinct for the reasons given above and the search required for each is not required for the others, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST).

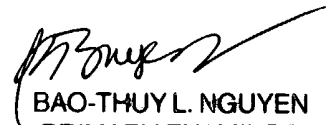
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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David J Venci
Examiner
Art Unit 1641

djv


BAO-THUY L. NGUYEN
PRIMARY EXAMINER
8/9/04